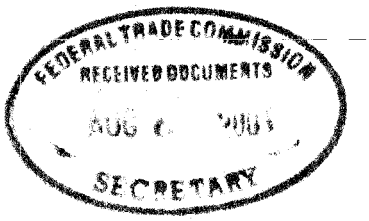
AMCP Academy of Managed Care Pharmacy



August 5, 2003

Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Ave. NW
Washington, DC 20580

Subject: Comments Regarding the June 26, 2003 Joint FTC-DoJ Hearings on Health Care and Competition Law and Policy (Pharmaceuticals: Formulary)

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide information to the Commission and Department staff as they examine the use of formularies in the provision of health care.

The Academy is a professional association of pharmacists who serve patients and the public by the promotion of wellness and rational drug therapy through the application of managed care principles and practices. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to the more than 200 million Americans served by managed care.

Because Academy members are directly involved in the development and maintenance of formulary management systems on behalf of PBMs, health plans and others, we believe our expertise and the materials we have developed will be of assistance to the staff of the Commission and Department. The Academy has helped to develop a consensus document outlining the Principles of a Sound Drug Formulary System. It represents the collaborative agreement of stakeholders concerned about formulary administration – physicians, pharmacists and patients. The Principles document can be found on the Academy website at: http://www.amcp.org/publications/drugformulary.pdf and is included with this letter.

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The Academy believes that, when properly implemented, formulary management serves as an integrated patient care process that enables health care professionals to work together to promote clinically sound, cost-effective pharmaceutical care. In the face of the escalating number and complexity of drug products, rising drug prices and direct-to-consumer advertising, the formulary management process provides the managed health care system with the ability to objectively differentiate between superior and marginal drugs. The formulary process is further explained in AMCP's concept series paper on formulary management, a copy of which is enclosed and which can be found on the AMCP website at: http://www.amcp.org/professional_res/concepts/form_man.asp.

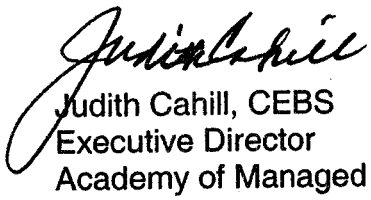
AMCP believes further that a well-designed, properly administered formulary will assist in the effective management of a patient's overall health care. A formulary improves quality of care by encouraging the use of medications that are demonstrated to be the safest, and most effective and will produce the most positive therapeutic outcomes for the patient. A copy of the Academy's position statement on formularies is enclosed and can also be found on the AMCP website at http://www.amcp.org/professional_res/position/013.asp.

The Academy has taken the lead in developing a tool to assist health plans, PBMs and government payors in formulary decision making. AMCP's *Format for Formulary Submission*, published in October 2000, is a set of guidelines for the evaluation of medications. The *Format* is helping to answer the oft-asked questions, "Which new drugs offer advantages at reasonable costs, thus providing good value?" AMCP's *Format* does not focus on reducing drug spending; in fact there will be cases where drug spending will increase. Rather the intent is for interested stakeholders to understand the value that they are getting for their pharmaceutical expenditures. Organizations that cover prescription drug services for millions of Americans have adopted the *Format*. For more information on the *Format* and its use by PBMs, please contact Marissa Schlaifer, AMCP Pharmacy Affairs Director, at (703) 683-8416 or mschlaifer@amcp.org.

The Academy also believes that government should encourage an environment in which PBMs and other managed care organizations can continue to use existing and develop new strategies to manage prescription drug benefits. Overly burdensome regulatory restrictions that limit their ability to do so will increase the cost of health care and could compromise the availability and affordability of the prescription drug benefit. The AMCP position statement on the regulation of pharmacy benefit management companies is enclosed and can also be found on the AMCP website at http://www.amcp.org/professional_res/position/017.asp.

The Academy appreciates the opportunity to provide information and comments and would be pleased to address any further questions that may arise. For additional information, I may be contacted at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,



Judith Cahill, CEBS
Executive Director
Academy of Managed Care Pharmacy

Principles of a Sound Drug Formulary System

These principles have been endorsed by the following organizations:

- Academy of Managed Care Pharmacy
- Alliance of Community Health Plans
- American Medical Association
- American Society of Health-System Pharmacists
- Department of Veterans Affairs,
  Pharmacy Benefits Management
  Strategic Healthcare Group
- National Business Coalition on Health
- U. S. Pharmacopeia

October 2000

Principles of a Sound Drug Formulary System

PREAMBLE

A coalition of national organizations representing health care professionals, government, and business leaders formed a working group (See Appendix III) to develop a set of principles specifying the essential components that contribute to a sound drug formulary system. The Coalition was formed in September 1999 in response to the widespread use of drug formularies in both inpatient and outpatient settings and the lack of understanding about formularies among the public. Also, proposed federal legislation that would provide a prescription drug benefit for Medicare beneficiaries has brought increased attention to the appropriate role and management of drug formulary systems within drug benefit programs.

The formulary system, when properly designed and implemented, can promote rational, clinically appropriate, safe, and cost-effective drug therapy. The Coalition has enumerated these principles, however, because it recognizes that patient care may be compromised if a formulary system is not optimally developed, organized and administered. This document contains "Guiding Principles" that the Coalition believes must be present for a drug formulary system to appropriately serve the patients it covers. The absence of one or more of these "Guiding Principles" should be cause for careful scrutiny of a formulary system. A glossary (See Appendix I) and bibliography (See Appendix II) are included with the "Guiding Principles" to clarify terminology and to provide additional resources, respectively.

The Coalition believes that the presence of consensus-based Formulary System Principles can assist decision-makers who must balance the health care quality and cost equation. Further, the Guiding Principles will be a valuable educational tool for national, state and local public policy makers, health care system administrators, purchasers and third party payers, practitioners, and consumers and patient advocates. These parties all have an interest in designing formulary systems that ensure patients have access to rational, clinically appropriate, safe, and cost-effective therapy and which supports an affordable and sustainable drug benefit program.

DEFINITIONS

Drug Formulary System - an ongoing process whereby a health care organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.

Drug Formulary - a continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists and other experts in the diagnosis and/or treatment of disease and promotion of health.

GUIDING PRINCIPLES

Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost effective drug therapy.

- Clinical decisions are based on the strength of scientific evidence and standards of practice that include, but are not limited, to the following:
  - Assessing peer-reviewed medical literature, including: randomized clinical trials (especially drug comparison studies), pharmacoeconomic studies, and outcomes research data.
  - Employing published practice guidelines, developed by an acceptable evidence-based process.
  - Comparing the efficacy as well as the type and frequency of side effects and potential drug interactions among alternative drug products.
  - Assessing the likely impact of a drug product on patient compliance when compared to alternative products.
  - Basing formulary system decisions on a thorough evaluation of the benefits, risks and potential outcomes for patients; risks encompass adverse drug events (adverse drug reactions and medication errors, such as those caused by confusing product names or labels).

- Economic considerations include, but are not limited, to the following:
  - Basing formulary system decisions on cost factors only after the safety, efficacy and therapeutic need have been established.
  - Evaluating drug products and therapies in terms of their impact on total health care costs.
  - Permitting financial incentives only when they promote cost management as part of the delivery of quality medical care. Financial incentives or pressures on practitioners that may interfere with the delivery of medically necessary care are unacceptable.

The formulary system encompasses drug selection, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, and monitoring of outcomes.

- The formulary system:
  - Provides drug product selection and formulary maintenance (see above).
  - Provides drug use evaluation (also called drug utilization review) to enhance quality of care for patients by assuring appropriate drug therapy.
  - Provides for the periodic evaluation and analysis of treatment protocols and procedures to ensure that they are up-to-date and are consistent with optimum therapeutics.
  - Provides for the monitoring, reporting, and analysis of adverse results of drug therapy (e.g., adverse drug reactions, medication errors) to continuously improve the quality of care.

GUIDING PRINCIPLES

The Pharmacy and Therapeutics (P&T) Committee, or equivalent body, comprised of actively practicing physicians, pharmacists and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products.

❖ The Pharmacy and Therapeutics Committee:

- Objectively appraises, evaluates, and selects drugs for the formulary.
- Meets as frequently as is necessary to review and update the appropriateness of the formulary system in light of new drugs and new indications, uses, or warnings affecting existing drugs.
- Establishes policies and procedures to educate and inform health care providers about drug products, usage, and committee decisions.
- Oversees quality improvement programs that employ drug use evaluation.
- Implements generic substitution and therapeutic interchange programs that authorize exchange of therapeutic alternatives based upon written guidelines or protocols within a formulary system. (Note: Therapeutic substitution, the dispensing of therapeutic alternates without the prescriber's approval, is illegal and should not be allowed-See Glossary.)
- Develops protocols and procedures for the use of and access to non-formulary drug products.

Physicians, pharmacists, and other health care professionals provide oversight of the formulary system.

- Health care organization policies should ensure appropriate oversight of the P&T Committee and its decisions by the medical staff or equivalent body.

The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members.

❖ Formulary system policies should:

- Require P&T committee members to reveal, by signing a conflict of interest statement, economic and other relationships with pharmaceutical entities that could influence Committee decisions.
- Exclude product sponsor representatives from P&T committee membership and from attending P & T committee meetings.
- Require P&T committee members to adhere to the formulary system's policy on disclosure and participation in discussion as it relates to conflict of interest.

GUIDING PRINCIPLES

The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities.

❖ The formulary system should:

- Inform physicians, pharmacists, other health care professionals, patients, and payers about the factors that affect formulary system decisions, including: cost containment measures; the procedures for obtaining non-formulary drugs; and the importance of formulary compliance to improving quality of care and restraining health care costs.
- Proactively inform practitioners about changes to the formulary or to other pharmaceutical management procedures.
- Provide patient education programs that explain how formulary decisions are made and the roles and responsibilities of the patient, especially the importance of patient compliance with drug therapy to assure the success of that therapy.
- Disclose the existence of formularies and have copies of the formulary readily available and accessible.
- Provide rationale for specific formulary decisions when requested.

The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.

❖ The formulary system should:

- Enable individual patient needs to be met with non-formulary drug products when demonstrated to be clinically justified by the physician or other prescriber.
- Institute an efficient process for the timely procurement of non-formulary drug products and impose minimal administrative burdens.
- Provide access to a formal appeal process if a request for a non-formulary drug is denied.
- Include policies that state that practitioners should not be penalized for prescribing non-formulary drug products that are medically necessary.

APPENDIX I
GLOSSARY

Drug Formulary System - an ongoing process whereby a health care organization, through its physicians, pharmacists and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost effective to best serve the health interests of a given patient population.

Drug Formulary - a continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Pharmacy & Therapeutics (P&T) Committee - an advisory committee that is responsible for developing, managing, updating, and administering the drug formulary system.

Generic Substitution - the substitution of drug products that contain the same active ingredient(s) and are chemically identical in strength, concentration, dosage form, and route of administration to the drug product prescribed.

Therapeutic Alternates - drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses.

Therapeutic Interchange - authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system.

Therapeutic Substitution - the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber. This is an illegal act because only the prescriber may authorize an exchange of therapeutic alternates.

Drug Utilization Review (Drug Use Review, DUR, and Drug Use Evaluation) - process used to assess the appropriateness of drug therapy by engaging in the evaluation of data on drug use in a given health care environment against predetermined criteria and standards.

APPENDIX II

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APPENDIX III
COALITION WORKING GROUP

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Public Comment Requested
To ensure that knowledgeable and interested parties beyond the Coalition Working Group had an opportunity to contribute to the Principles development process, a preliminary set of principles was distributed for public comment to 50-plus organizations in February 2000. Comments received were thoroughly reviewed and considered by the Coalition Working Group.

Where We Stand

Regulation of Pharmacy Benefit Management Companies

AMCP Academy of Managed Care Pharmacy®

Where We Stand

The Academy of Managed Care Pharmacy believes that government should encourage an environment in which pharmacists working within managed care organizations, including pharmaceutical benefit management companies, can continue to develop innovative and integrated strategies to manage prescription drug benefits for a given patient population. The Academy opposes statutory and regulatory proposals that unduly restrict the ability of pharmacists working within managed care organizations from utilizing tools and services that are essential for the management of a prescription drug benefit. These types of proposals are objectionable if they go beyond procedural protections and enter an arena traditionally within the purview, expertise and experience of health care professionals. The imposition of such restrictions potentially incapacitates managed care pharmacists from considering the range of clinical, legal, quality-of-life, safety and pharmacoeconomic factors which form the basis for the design and implementation of effective drug benefit strategies and programs. The goals of these strategies and programs are to improve the delivery of patient-oriented pharmaceutical care and restrain the increases in the cost of prescription drugs.

Economic realities, safety issues associated with potentially dangerous medications, patient noncompliance with drug regimens and other pragmatic considerations require that managed care pharmacists, physicians, nurses and others have broad latitude in structuring drug benefit programs. Proposals that would limit the flexibility to use existing and develop new strategies could have unintended consequences. Unnecessary or overly burdensome regulatory restrictions could place patients at risk and increase the cost of health care. The result could compromise the availability and affordability of the prescription drug benefit. The benefits could be reduced or made available to a smaller patient population or the benefit itself could be eliminated.

The ability to develop programs and utilize tools and services to manage prescription drug benefits helps to assure that the benefit is affordable for both patients and purchasers. It further helps assure the benefit is delivered in a manner designed to optimize achieving therapeutic outcomes desired by patients and the health care professionals responsible for their care. Providing appropriate flexibility will mean that pharmacists and other health care professionals can respond to a complex and continually changing health care delivery system.

If you have any questions, please call the AMCP office at (703) 683-8416 or (800) 827-2627. ◆

Approved by the AMCP Board of Directors, April 3, 2002

About AMCP

The Academy of Managed Care Pharmacy (AMCP) is a professional association of pharmacists and associates who serve patients and the public by the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to the more than 200 million Americans served by managed care. More news and information about AMCP can be obtained on their website, at www.amcp.org.

AMCP Academy of Managed Care Pharmacy®

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Where We Stand

Formularies

AMCP Academy of Managed Care Pharmacy®

Where We Stand

The Academy of Managed Care Pharmacy (AMCP) supports the use of appropriately designed formularies as quality-enhancing, cost-effective pharmaceutical care tools.

A drug formulary is a continually updated list of prescription medications which represent the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. Formularies often contain additional prescribing and clinical information that assists health care professionals as they promote high quality, affordable care to patients. Formularies have existed for decades and are most commonly used by hospitals, health plans, pharmacy benefit management companies (PBMs), self-insured employers, and government agencies (including the Department of Veterans Affairs, Department of Defense, and many state Medicaid programs).

AMCP supports a well designed and properly administered formulary to assist in effectively managing a patient's total medical care regimen. A formulary enhances quality of care by encouraging the use of those prescription medications that are demonstrated to be the safest, most effective, and produce positive patient outcomes.

A formulary works best when it supports and operates in conjunction with other tools that promote quality and optimal results such as drug utilization review, and medical treatment guidelines. In addition, the value of a formulary is maximized when it is part of an integrated patient care process which encourages physicians, pharmacists, and other caregivers to work together to ensure positive and cost-effective results.

The following elements should be considered when developing and operating a formulary:

- As part of the process by which a formulary is developed and maintained, a Pharmacy & Therapeutics Committee or equivalent entity should be established and meet regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experi-

ence, economic data, and provider recommendations to determine which drugs are the safest, most effective, and produce best medical results. The membership of a P&T Committee should include physicians, pharmacists and other health care professionals and should, collectively, have current knowledge and expertise in clinical aspects of prescription drugs and drug use review, evidence-based decision making, evaluation, and intervention. AMCP supports the use of its *Format for Formulary Submissions*[1] and the *Principles of a Sound Drug-Formulary System*[2] to ensure accuracy and completeness of the information reviewed.

- A formulary is a dynamic and continually revised document. The P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices, and new clinical and economic evidence that may have an impact on which drugs are included or excluded.
- A formulary supports and maximizes the effectiveness of prescribing guidelines and protocols for physicians and other prescribers.
- Formulary decisions have an impact on all components of the health care delivery system. Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, better patient adherence to the treatment plan, fewer adverse side effects and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer's access to more affordable care, and provides the patient with an improved quality of life.
- The primary criteria for the formulary decision-making process should be centered on a drug's safety, efficacy and effectiveness. A drug's clinical profile, rather than its costs, should be the primary factor in determining whether a drug is included or excluded from a formulary. Members of the P&T Committee should use evidence-based decision-making tools and models which relate key factors and probabilities to one another in order to determine the best drugs to have on the formulary. Inputs into this process include clinical trials, scientific studies, an evaluation of the drug's role in disease treatment guidelines, comparisons with other like products, and data which reflects the drug's actual or projected utilization in specific patient populations. In addition, the formulary review process has evolved from one requiring typical efficacy and safety data to one requiring data on health outcomes and actual effects and costs of a drug once it has been commercially released in the "real world."
- For quality assurance purposes, health plans that use formularies should have policies in place to provide for a medical exceptions process. The medical exceptions process allows individuals to request:
  - coverage of a prescription drug that is not covered based on the formulary
  - continued coverage of a drug that has been discontinued for reasons other than safety or because the drug cannot be supplied or has been withdrawn from the market.

  Such exceptions should be based only on documented medical need.

Please see AMCP's website, www.amcp.org, for revisions and updates to our "Where We Stand" series. ◆

Revised by the AMCP Board of Directors
February 2003

Revised by the AMCP Board of Directors
February 1997

Approved by the AMCP Board of Directors
February 1994

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[1] Academy of Managed Care Pharmacy, *Format for Formulary Submissions: A Format for Submission of Clinical and Economic Data in support of Formulary Consideration by Health Care Systems in the United States* (Alexandria, VA: 2002).

[2] *Principles of a Sound Drug-Formulary System*, consensus document. October 2000. http://www.amcp.org/publications/drug formulary.pdf.

About AMCP

The Academy of Managed Care Pharmacy's (AMCP's) mission is to empower its members to serve society by using sound medication management principles and strategies to achieve positive patient outcomes. AMCP has more than 4,800 members nationally who provide comprehensive coverage and services to the more than 200 million Americans served by managed care. More news and information about AMCP can be obtained at www.amcp.org.

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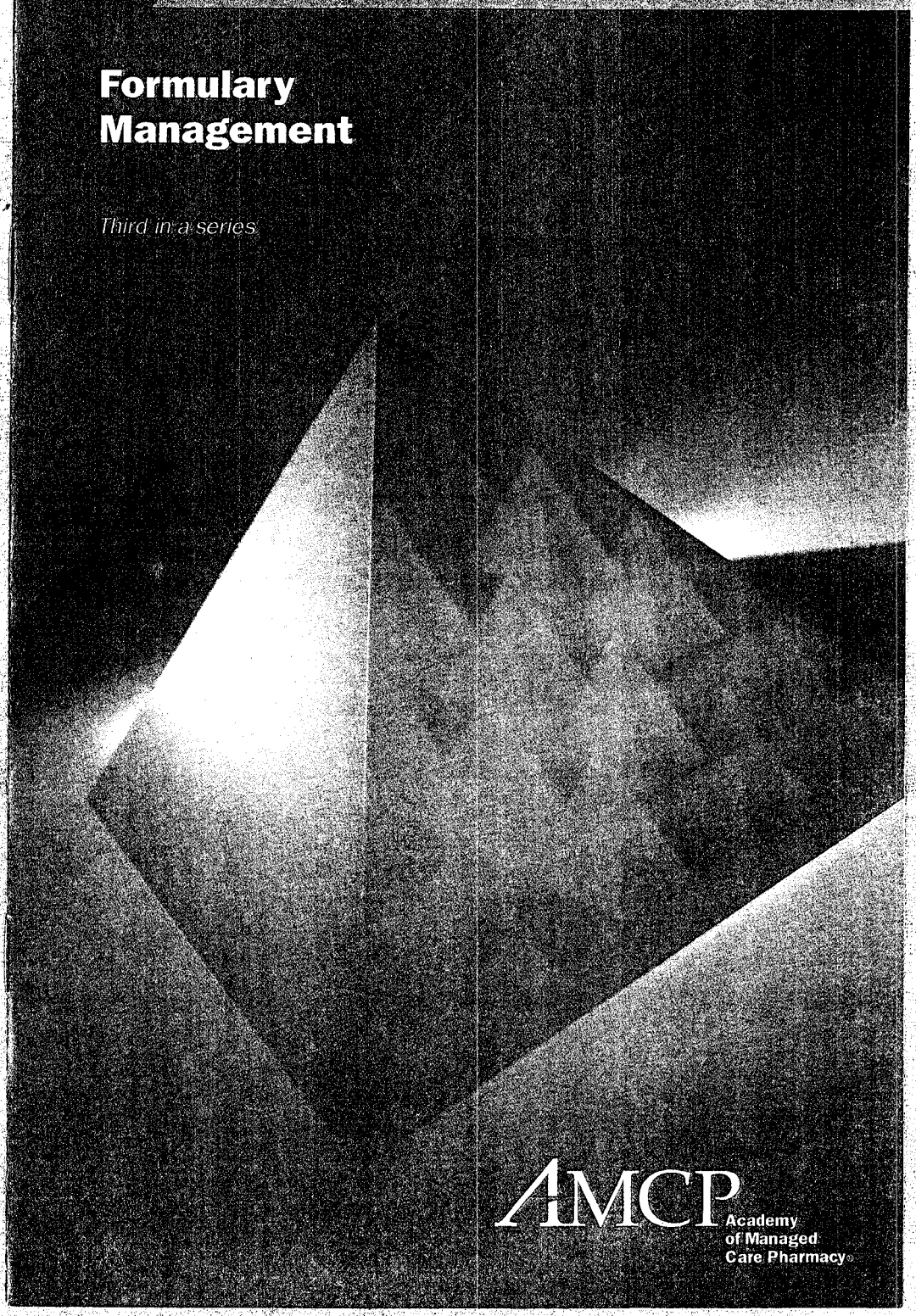
Concepts in Managed Care Pharmacy

Formulary Management

Third in a series



AMCP Academy of Managed Care Pharmacy®

About AMCP

The Academy of Managed Care Pharmacy (AMCP) is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy by the application of managed care principles. The mission of AMCP is to serve as an organization through which the membership pursues its common goals; to provide leadership and support for its members; to represent its members before private and public agencies and health care professional organizations; and to advance pharmacy practice in managed health care systems.

The Academy now has more than 4,500 members nationally who are part of more than 600 health care organizations that provide comprehensive coverage and services to the 150 million Americans served by managed care.

AMCP's Concepts in Managed Care Pharmacy: A Series

AMCP's Concepts in Managed Care Pharmacy Series is designed to:

- Explain pharmacy terms and phrases in plain English
- Describe clearly and concisely how these concepts are implemented in the managed care setting

Contact AMCP for information on additional concept papers.

Formulary management is an integrated patient care process which enables physicians, pharmacists, and other health care professionals to work together to promote clinically sound, cost-effective pharmaceutical care.[1]

What is a Formulary?

A drug formulary is a continually updated list of medications which represent the current clinical judgement of physicians and other experts in the diagnosis and treatment of disease and preservation of health. Initially developed by hospitals in the 1950s as a management tool, the formulary was quickly adopted as a means to ensure that physicians had an adequate and consistent supply of medication for their day-to-day needs. The primary purpose of the formulary is to discourage the use of marginally effective drugs and treatments.

With the shift of health insurance to managed care, formularies have evolved into a formal system of managed care tools for assuring the selection of medications that have been demonstrated to be safe, effective, and affordable while maintaining or improving quality patient care. Formularies are now routinely used not only by hospitals, but by health plans, pharmacy benefit management companies (PBMs), self-insured employers and government agencies (including the Veterans Health Administration, Department of Defense, and most Medicaid programs).

A formulary system is much more than a list of medications that are approved for use by a managed health care organization. The system includes the methods which the organization uses to evaluate and select the medications for different diseases, conditions, and patients. Policies and procedures for the procuring, dispensing, and administering of the medications are also included in the system. Formularies often contain additional prescribing guidelines and clinical information which assists health care professionals to promote high quality, affordable care for patients. Finally, for quality assurance purposes, managed health care systems that use formularies have policies in place to give physicians and patients access to non-formulary drugs where medically necessary.

Formulary Development

Decisions on which drugs are included on a formulary are made by a Pharmacy and Therapeutics (P&T) Committee. The P&T Committee is responsible for developing, managing, updating, and administering the formulary. P&T Committees are comprised of primary care and specialty physicians, pharmacists, and other professionals in the health care field. Often, P&T Committees include nurses, legal experts, and administrators.

Due to the multiplicity of drugs on the market and the continuous introduction of new drugs into the market, a formulary must be a dynamic and continually revised document. In order to keep a formulary current, the P&T Committee meets regularly to review:

- Medical and clinical literature including clinical trials,
- Relevant patient utilization and experience,
- Current therapeutic guidelines and the need for revised or new guidelines,
- Economic data,
- Provider recommendations, and
- The safest, most effective drugs that will produce the desired goals of therapy at the most reasonable cost to the health care system.

P&T Committees look first for medications that are clinically effective. When two or more drugs produce the same clinical results in patients, then business elements like cost, supplier services, and ease of delivery are considered when determining which agent to include on the formulary.

Types of Formularies

Formularies are categorized according to their reimbursement structure. Factors such as the type of managed care plan, the size of the organization, its service objectives and drug benefit provisions, staff availability, and resources to manage the formulary will determine which of the following types of formularies best serves the needs of the health plan's members.

• **Open Formulary:** The payer provides coverage for all medications regardless of whether or not they are listed on the formulary. The payers include the health plan, the employer, or a pharmacy benefit management company (PBM) acting on behalf of the health plan or employer. However, some drugs such as those for cosmetic use or over-the-counter drugs may be excluded from coverage by plan design. Physicians are encouraged to prescribe formulary agents. Patients may or may not incur additional out-of-pocket expenses for using non-formulary drugs.

• **Closed Formulary:** Non-formulary drugs are not reimbursed by the payer. Administrative procedures are used to allow patients and physicians reimbursement for and access to non-formulary medications where medically appropriate.

• **Partially/Selectively Closed Formulary:** This is essentially an open formulary with either a few selected drugs that are not covered, or one in which reimbursement might be denied for an entire class of drugs such as those for cosmetic purposes or weight loss. Guidelines may be developed in which only specific physician specialists may prescribe a certain medication. These are usually very expensive medications which require a high level of expertise in prescribing and in monitoring treatment. Exception policies and procedures ensure that coverage for these select drugs is granted where medically necessary. New drugs are usually covered by the health plan until the P&T Committee decides which ones will be reimbursed.

Formularies Complement Other Health Care Management Tools

A formulary is one component of health care management. It enhances other existing pharmaceutical care practices designed to optimize patient care, including:

• **Sound medical treatment and prescribing guidelines or protocols:** Also called critical pathways or therapeutic guidelines, these recommended series of actions concerning a specific disease or condition involve drug therapy and all other aspects of patient care such as laboratory tests, x-rays, and surgery. They enhance consistency, improve quality of care, and improve outcomes for patients while reducing costs.

• **Drug utilization review and drug use evaluation programs:** These reviews of patient data evaluate the effectiveness, safety, and appropriateness of drug use and often alert clinicians about prescribing and drug regimen problems and about patients who may be inappropriately taking drugs that can produce an undesirable reaction or create other medical complications.

- **Physician, pharmacist, and patient drug education programs:** The success of the formulary system is largely dependent on its educational component. Physicians, pharmacists, patients, and other health care professionals must understand the rationale behind formulary decisions. The formulary education process must continuously provide the following:
  - Drug information monographs, newsletters, and in-service training to furnish physicians with information needed to provide a high standard of care.
  - Pharmacist education regarding changes in formulary content or policy, along with the rationale behind the formulary changes to ensure greater formulary compliance.
  - Patient education which explains how decisions are made, the role of the patient, and the importance of formulary compliance to both the patient and the managed health care system.

The Role of the Pharmacist

Pharmacists are key to the success of formulary management. Pharmacists have the knowledge and skills to coordinate the activities of the P&T Committee and have the expertise to lead formulary management initiatives and make recommendations based on sound clinical judgement.

To ensure the success of the formulary management process, pharmacists guide P&T Committees through the steps of deciding whether or not a drug should be included on the formulary and development of drug benefit-related policy and therapeutic guidelines. In addition, pharmacists:

- Determine the P&T Committee agenda;
- Analyze and disseminate scientific, clinical, and health economic information for P&T Committee member review;
- Record and archive P&T Committee meeting minutes;
- Follow-up with research when necessary; and
- Communicate P&T Committee decisions to health plan prescribers, other health care professionals, and patients, as appropriate.

The Importance of the Formulary Management Process

Providers and payers recognize that a team approach involving physicians, pharmacists, and other health care professionals working together to coordinate patient care produces the best clinical, humanistic, and economic outcomes.[2]

Formulary decisions impact all aspects of health care management. In the face of the escalating number and complexity of drug products, rising drug prices, and direct-to-consumer advertising, the formulary management process provides the managed health care system with the ability to objectively discriminate between superior and marginal drugs. Such efficient and effective use of health care resources can minimize overall medical costs, improve health plan member access to more affordable care, and provide an improved quality of life.

References

[1] Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Pharmaceutical Care.* 1997.

[2] Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Disease State Management.* 1998.

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